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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/103,355	06/23/1998	PETER J. KUSHNER	23070-080510	2899

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/10/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/103,355

Applicant(s)
Kushner et al.

Examiner
Michael Pak

Art Unit
1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Amendments filed 17 September 2002 (Paper No. 23) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 17 September 2002 (Paper No. 23), have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite the term "nuclear transcription factor ligand" whose metes and bounds are not clear. The specification on page 6, line 1, define "nuclear transcription factor ligand" as a compound that binds to a nuclear transcription factor. The specification on page 5, line 30, define "nuclear transcription factor" as referring to members of the nuclear transcription

factor superfamily. Neither the claims nor the specification provides any structural limitation which limits the metes and bounds of the term. Claims 2-13 are dependent on claim 1.

Claim 1 recite the term "cognate receptor" whose metes and bounds are not clear. The specification on page 6, line 13, define "cognate receptor" as a receptor of the type that is typically bound by the transcription ligand in question. Neither the claims nor the specification provides any structural limitation which limits the metes and bounds of the term. Claims 2-13 are dependent on claim 1.

Claim Rejections - 35 USC § 112, first paragraph

5. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 recite the newly amended claim limitation "wherein said cognate receptor is a receptor other than the estrogen receptor, AP-1, fos or jun" which is new matter not disclosed in the specification. The specification does not teach the negative limitation subgeneric claim.

6. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that issue as set forth in *Enzo* is that the language of the specification ... must describe the claimed invention so that one skilled in the art can recognize what is claimed. However, the terms without structure does not set forth the metes and bounds as discussed above and regardless of a product or a method claim the claim limitation without structure cannot be envisioned by one of skilled in the art.

7. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods with specific species of estrogen receptor and Markush group of cognate receptors in claim 7 which are functional, but does not reasonably provide enablement for the claimed method using cognate receptors or estrogen receptor or Markush group of cognate receptors in claim 7 which are not

functional. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that because the claims are drawn to methods the methods will be practiced regardless of whether the non-enabling product is used such as orphan receptors or variants. However, a genus claim which encompasses a large number of non-enabling claims is not enabled. As discussed above the metes and bounds of the generic terms are not clear and one of skilled in the art cannot practice the generic invention with a generic claims with a large number of non-enabling inventions. One skilled in the art cannot envision the generic claim limitations which are needed to practice the method claims rendering the generic method claim non- enabling.

Claim Rejections - 35 USC § 103

8. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushner et al.((AB); U.S. 5,723,291) in view of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), GAUB et al.((AV); Cell, 1990), Webb et al.(CB) and

Kushner et al. ((AD); WO 95/06754).

The reason for the rejection has been set forth in the previous office action.

Applicants argue that Kushner is not prior art under 103(c) because the application were under a common obligation of assignment at the time the invention was made. However, MPEP 706.02(1)(2) define common ownership and Kushner was owned by University of California whereas the present application owned by both Karo and University of California. Thus it does not meet the common ownership defined in MPEP 706.02(1)(2) because it is not 100% owned.

Double Patenting

9. Claim 8 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-27 of U.S. Patent No. 5,723,291 in view of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), GAUB et al.((AV); Cell, 1990), Webb et al.(CB) and Kushner et al.((AD); WO 95/06754). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that hindsight motivation was used. However, three separate motivations have been provided including a motivation from the primary reference. The motivation does not have to be the one used in the specification by the applicant but can be one recognized in the arts.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are cumulative references with Kushner et al.((AB); U.S. 5,723,291), Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990).

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of

rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
4 February 2003